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Biosafety Practices and Emergency Response at the Idaho National Laboratory and Los Alamos National Laboratory

Emergency Management and Robotics for Hazardous Environments

Frank F. Roberto
Dina M. Matz

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BIOSAFETY PRACTICES AND EMERGENCY RESPONSE AT THE IDAHO NATIONAL LABORATORY AND LOS ALAMOS NATIONAL LABORATORY

Frank F. Roberto, PhD, CBSP, and Dina M. Matz, CIH, CSP, CBSP

Idaho National Laboratory, P.O. Box 1625, Idaho Falls, ID 83415, francisco.roberto@inl.gov
Los Alamos National Laboratory, P.O. Box 1663, Los Alamos, NM 87545, dinas@lanl.gov

Strict federal regulations govern the possession, use, and transfer of pathogens and toxins with potential to cause harm to the public, either through accidental or deliberate means. Laboratories registered through either the Centers for Disease Control and Prevention (CDC), the U.S. Dept. of Agriculture Animal and Plant Health Inspection Service (USDA/APHIS), or both, must prepare biosafety, security, and incident response plans, conduct drills or exercises on an annual basis, and update plans accordingly. At the Idaho National Laboratory (INL) and Los Alamos National Laboratory (LANL), biosafety, laboratory, and emergency management staff have been working together to satisfy federal and U.S. Dept. of Energy (DOE)/National Nuclear Security Administration (NNSA) requirements. This has been done through the establishment of plans, training, tabletop and walk-through exercises and drills, and coordination with local and regional emergency response personnel. Responding to the release of infectious agents or toxins is challenging, but through familiarization with the nature of the hazardous biological substances or organisms, and integration with laboratory-wide emergency response procedures, credible scenarios are being used to evaluate our ability to protect workers, the public, and the environment from agents we must work with to provide for national biodefense.

I. INTRODUCTION

The DOE/NNSA national laboratories across the U.S. have a long history supporting technology development to ensure our nation's security. Prior to the anthrax events of 2001 (sometimes called "Amerithrax") the national labs were already at work on detection and countermeasures for biological warfare and bioterrorism. This work has frequently required at least the incidental use of live biological agents or toxins that are currently governed by federal regulations and DOE directives. It is important to note, however, that at a fundamental level, the national labs employ well-accepted practices and philosophies for safe work and emergency response related to controlling exposure to etiologic (disease-causing) biological agents that are part of the biological safety discipline. This paper will describe the integration of biological safety (biosafety) and emergency planning at two DOE/NNSA national laboratories working with federally-regulated select agents.

II. REGULATORY FRAMEWORK SURROUNDING WORK WITH SELECT AGENTS

Etiologic agents and toxins that are considered to pose a severe threat to human, animal, and/or plant health, and that can "be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purpose" have been classified as select agents and toxins[1]. Prior to 2001 and the enactment of the *USA Patriot Act*, etiologic agents were regulated primarily with respect to interstate shipment[2]. In response to the *Antiterrorism and Effective Death Penalty Act of 1996*[3], the Centers for Disease Control and Prevention (CDC) proposed changes to the federal regulation, creating for the first time, a list of select agents[4] and requiring registration of facilities transferring or receiving select agents. By incorporation into the regulation, the guidelines provided in the CDC publication *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*)[5] became legal requirements of registered facilities in January, 2002.

After the Amerithrax incidents in 2001, Congress enacted additional legislation that in part, focused on future prevention of similar bioterrorism acts. The *USA Patriot Act* and the *Public Health Security and Bioterrorism Preparedness Response Act of 2002*[6] in particular legislated provisions requiring HHS and APHIS to enhance regulations controlling access to select agents. The end result are the current regulations governing select agent and toxin use (hereafter referred to as 42 CFR 73)[7,8]. An updated 5th edition of the BMBL has also been released on-line[9]. At the time this manuscript was prepared, however, inspectors were still using the 4th edition to evaluate compliance.

DOE/NNSA has also been concerned about the expansion of research and development activities across the national lab complex utilizing select agents. In 2001, DOE/NNSA's Office of Worker Protection Policy issued DOE Notice 450.7[10], requiring DOE contractors to comply with applicable regulations, establish institutional biosafety committees (IBCs; note that IBCs have traditionally been required at academic institutions to oversee recombinant DNA research receiving support from NIH, but are being tasked with independent review of work with biohazards with increasing frequency), implement best practices, with specific reference to the BMBL, establish immunization policies based on HHS recommendations, and other administrative requirements designed to ensure that the responsible DOE field elements were aware of the work and agents in use. This notice was extended until 2006, at which time the requirements were largely incorporated into DOE's Worker Safety and Health Program (also a federal regulation)[11].

The emergency planning aspects of compliance with 42 CFR 73 (§73.14, Incident Response) were incorporated into the comprehensive, all-hazards emergency management requirements for DOE/NNSA facilities with the issuance of DOE Order 151.1C, *Comprehensive Emergency Management System*[12]. A separate Emergency Management Guide[13] has also been issued to assist site emergency management personnel in planning for and appropriately managing biological hazards including select agents and toxins.

III. THE BIOSAFETY DISCIPLINE PROVIDES AN APPROACH TO SAFE WORK WITH SELECT AGENTS

One could argue that biosafety practices have been developed and refined since the pioneering work of Louis Pasteur in the 19th century. Effective biosafety involves a tiered approach to controlling and containing infectious agents, starting with the laboratory worker (laboratorian in CDC vernacular) and their practices and procedures. These practices should be designed to minimize the potential for release of infectious materials into the workplace, and exposure of personnel. The BMBL requires that such practices be documented in *a lab-specific* biosafety plan. Personal protective equipment (PPE) is selected to provide barriers to immediate exposure to spills or splashes, and depending on routes of exposure and infectious potential of the agent(s), may include respiratory protection or even full containment suits. Engineered controls such as biosafety cabinets (BSC: HEPA filtered cabinets, the most common of which will provide both worker and material protection), negative air pressure lab environments, antechambers and showers, and HEPA-filtered room exhaust systems provide additional assurance that potential spills or other releases would be contained to the affected laboratory. Finally, administrative controls, including access restrictions, escort requirements, vaccination policies, and others, ensure that exposure risk is limited as much as possible to trained personnel who are further protected by available vaccines and undergo additional health surveillance. Most readers will be familiar with the biocontainment levels associated with use of potentially infectious materials, ranging from biosafety level 1 to 4 (BSL-1to 4), and roughly corresponding to the relative risk of agents that may be employed at each level, from posing little or no risk to healthy individuals (BSL-1) to agents with no available prophylaxis or treatment, and likely to cause significant mortality or morbidity, often with unknown routes of transmission (BSL-4). It should be noted that operations conducted at each respective biosafety level include selection of appropriate practices, procedures, PPE, engineering, and administrative controls, and that it is the aggregate of these controls, rather than any single control, that defines the containment level. Selection of the appropriate biocontainment level is also dependent on several factors, including the infectious potential of the agent in question, the severity of disease, persistence/survival upon release, available countermeasures, and the nature of the work to be performed with the agent.

The purpose of this brief discourse on principles of biosafety is to demonstrate that under normal circumstances, there are multiple controls in effect to protect workers, the public, and the environment from accidental release of infectious agents, and some protection in the event of an off-normal event. Laboratory design features, such as inward-flowing air exhausted through dedicated exhaust stacks and HEPA filters, commonly found in BSL-3 and –4 laboratory facilities, can be important components of biocontainment labs providing additional assurance in the case of lab accidents. However, catastrophic events may have the potential to breach even the most robust engineered containment, and the possibility of deliberate, intentional release by action of individuals or organizations must now also be considered.

IV. PLANS, TRAINING, TABLETOP AND WALK-THROUGH EXERCISES AND DRILLS, AND COORDINATION WITH LOCAL AND REGIONAL EMERGENCY RESPONSE PERSONNEL.

Exercises and drills at INL and LANL have proven to be extremely beneficial in several ways. First, they meet regulatory requirements for select agent and DOE requirements for emergency drills and exercises. Second, they provide a no-fault environment where exercise participants have the ability to assess, identify, openly discuss, train, and learn their respective emergency response capabilities to provide support during an emergency biological incident. Lastly, they assist research, facility, and safety personnel in the development of short and long range improvement plans. The progression from table top, to focused drills, to limited or full site exercises provides opportunity at each step to further improve processes. This results in better preparation should an actual emergency occur.

IV.A. IDAHO NATIONAL LABORATORY DRILLS AND EXERCISES

Emergency planning for biocontainment facilities at the INL has required coordination with both internal and external organizations from the outset, because first response at these facilities is currently the responsibility of our local fire municipal department. This means that unlike many emergencies (even at our own site) where DOE facilities are largely self-sufficient with respect to emergency response, a local agency is likely to control the initial emergency through the incident command system.

We engaged first responders, regional hazardous materials (hazmat) teams, public health, site protective forces, technical subject matter experts, facility engineers, and emergency planners as we created the first detailed incident response plan necessary to comply with 42 CFR 73. Since that first meeting, where a draft of the proposed incident response plan was used to talk through an emergency scenario and evaluate what might be missing or improved, several walk-through drills and one multi-agency, full dress response exercise have been conducted. Each one has identified responses and interactions that can be improved, but each one has also increased the confidence of the respective agencies in understanding the nature of the scenarios, and their ability to respond.

Any emergency scenario involving select agents moves through a sequence of events initiated by the determination that a release of some kind has occurred. For select agents, that release can be the result of an off-normal situation in the laboratory (spill, accident, equipment disruption, power outage), an intentional release resulting from criminal action, accidental or intentional release, theft, or loss detected days or weeks after the release event, or a catastrophic event resulting in release and substantial destruction of the facility. Table I provides a set of possible scenarios that can be used to consider who needs to be involved, and what the proper actions might be. A few of these examples will be discussed further below incorporating some of the lessons learned.

Table I. Example Off-normal Event Scenarios, Players, and Response Actions

Event Description	**Likely Participants**	**Actions**
Lab spill	Lab staff, RO, occupational medicine, CDC, APHIS	Contain, evacuate lab if necessary; determine if additional support is necessary; notify CDC or APHIS if primary containment barriers breached; monitor exposed employees; evaluate value of prophylaxis
Theft or Loss	Lab staff, RO, law enforcement, CDC, APHIS,	Notify CDC, APHIS; if theft is evident, engage law enforcement; execute search for missing inventory with lab staff
Disease detected in community	Lab staff, RO, public health, law enforcement, CDC, APHIS	Notify CDC, APHIS (may already be involved); determine if event is result of deliberate or accidental release; if accidental, begin systems and process evaluation to determine causes; monitor at-risk population; evaluate value of prophylaxis

Table I. Example Off-normal Event Scenarios, Players, and Response Actions

Event Description	Likely Participants	Actions
Catastrophic Release	Lab staff, RO, facility engineers, site emergency management, fire department, law enforcement, regional hazmat, public health, CDC, APHIS	Evacuate during business hours; account for staff; rescue if necessary; establish decon; contain building systems; notify CDC, APHIS; estimate amount of release and protective actions; assess extent of contamination; initiate law enforcement investigation if necessary; establish restoration and recovery plan after stabilization; monitor at-risk population; evaluate value of prophylaxis
Disgruntled employee steals and releases agent	Lab staff, RO, law enforcement, CDC, APHIS, public health	Notify CDC, APHIS; estimate amount of release and population at risk; contain and decontaminate if possible; initiate investigation; monitor at-risk population; evaluate value of prophylaxis

For laboratory incidents (assuming the event occurs during the course of normal activities), training of the laboratory worker to take immediate actions to contain and inactivate the agent if possible is of paramount importance. Proper training, practices, and procedures are obviously critical. Recognition of events that would exceed the capabilities of the individual worker or team to deal with is also important, and as in any emergency, life protection must supercede any other protective actions. Exposed personnel should be isolated for decontamination, and identified for medical evaluation, follow-on monitoring, and need for prophylaxis. First responders should have been called in if the situation warranted (medical emergency, fire, or explosion impacting a biocontainment lab, for example). At this point, additional support can be called upon, depending on the nature of the event. Should a release breach the secondary biocontainment barriers, site emergency management plans coordinated with DOE/NNSA headquarters are activated, leading to the declaration of an unclassified Operational Emergency (OE).

42 CFR 73 mandates that the facility Responsible Official (RO) or designee (many facilities have alternate ROs) be involved to support emergency actions, and notify the appropriate regulatory agency (CDC or APHIS), law enforcement, and public health agencies as necessary. Therefore, a quick assessment as to the nature of the select agent emergency can identify the outside agencies that will need to be notified beyond those that might be engaged in any DOE operational emergency. The appropriate regulatory agency must also be notified immediately in the event of an occupational exposure, or release beyond the primary barriers of the biocontainment area (42 CFR §73.19(b).

From Table 1, it can be seen that lab staff and the RO will have involvement in virtually every scenario, if for no other reason than they possess the best knowledge of what agents are involved and how much agent might have been released (perhaps one of the most difficult challenges, as current models of biological agent dispersal are based upon a large quantity of infectious material or toxin being released, rather than considering an accidental release from a building with complex spaces and ventilation paths).

In the case of the INL, first responders will arrive within minutes after notification, and establish an incident command post. With the information that a biological incident has occurred, the regional hazmat team will be called in to support the municipal fire department, including equipment for decontamination of personnel, and response staff with PPE better suited to the demands of a biological event. These teams would be called into play after rescue and fire abatement activities are concluded and the facility is deemed safe for emergency personnel re-entry.

Deliberate events will also result in a substantial law enforcement role, and add additional chain of custody issues to any necessary environmental sampling that might be conducted to assess the extent of contamination or boundaries of an event. Site protective forces and local law enforcement will likely be engaged from the outset of any emergency to control traffic and site access, but intentional release of select agents is by definition a federal crime, so regional and national law enforcement personnel will respond as well when circumstances dictate.

Should the on scene assessment indicate that a substantial release has occurred, it is likely that infectious materials will have moved beyond the facility boundaries, in which case the incident commander will need information to determine if evacuation of other workers or the public is warranted. Public health should also be engaged in considering the nature of the agent involved, and what community health surveillance and/or prophylaxis they would direct. These actions are not under the control of DOE, and may also be supported with national resources from CDC or APHIS.

After the event has been stabilized, determination of the extent of contamination and need for decontamination must be made. This can be difficult since the capabilities for sensitive detection of biological agents and the appropriate facilities in which to perform such analyses may have been compromised by the event itself. All state public health labs are members of the CDC Laboratory Response Network (LRN)[14], and receive training and undergo proficiency testing to identify many select agents. However, those labs may be hours away from the incident scene, so pre-planning for the types of agents that might be involved is an important consideration for emergency preparedness.

It is evident from this brief analysis of a few potential emergency scenarios that there are some incidents that will be well within the abilities of immediate lab staff to deal with, while situations in which catastrophic damage has occurred to facilities as a result of fire or explosion may engage substantial resources beyond the DOE/NNSA facilities themselves. Even natural disasters, such as Hurricane Katrina, affected select agent laboratories, requiring interagency coordination to determine a proper course of action to contain the biological threat. The need for adequate pre-planning for emergencies, as required by 42 CFR 73 and applicable DOE directives is clear. Our drills and exercises have also highlighted the importance of engaging all agencies that might have a role in the eventual response so that roles and responsibilities are understood, and to ensure that lines of communication are established well before any real emergency.

IV.B. LOS ALAMOS NATIONAL LABORATORY DRILLS AND EXERCISES

Table top exercises, drills, and full scale exercises at LANL with specific focus on biological hazards have resulted in identification of strengths, as well as opportunities for improvement for emergency response to these types of emergencies.

Emergency Operations at LANL also benefit from having personnel with biosafety expertise within the Emergency Operations Center to communicate directly with incident command and hazmat personnel in the field regarding potential exposure routes, environmental sampling techniques, decontamination procedures and personal protective equipment specific to an organism.

V. SUMMARY

The biosafety discipline provides an approach to safe work with select agents. It also provides emergency operations personnel with a framework to identify, evaluate, and control exposures to biological agents in the event of an actual emergency involving a biological agent. Plans, training, tabletop and walk-through exercises and drills, and coordination with local and regional emergency response personnel provide an excellent opportunity for a facility to identify strengths and opportunities for improvement in emergency response to biological incidents.

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